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BROOKS, CAMERON & HUEBSCH, PLLC
1221 NICOLLET AVENUE
SUITE 500
MINNEAPOLIS, MN 55403

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JUAN I. PEREZ, MATTHEW J. FITZ, ROBIN W. ECKERT, OCTAVIAN IANCEA, RICHARD NEWHAUSER, DAVID T. POLLOCK, and TIMOTHY A.M. CHUTER

Appeal 2009-015402
Application 10/091,172
Technology Center 3700

Before ERIC GRIMES, FRANCISCO C. PRATS, and STEPHEN WALSH, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims to a system for treating vasculature at a repair site. The Examiner rejected the claims as obvious.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claims 1-9, 12-22, 24, and 25 stand rejected and appealed. (App. Br. 3).[2] Claim 1 is representative and reads as follows:

> Claim 1: A system for treating vasculature at a repair site, comprising: a first treatment component;
>
> a first sheath having the first treatment component and configured to receive a subsequent treatment component after the first sheath is placed within the vasculature and the first treatment component is deployed, the first sheath having an inferior end and a length sufficient to extend to a repair site within the vasculature; and
>
> a loading capsule configured to receive a subsequent treatment component, wherein the loading capsule includes a superior terminal end that is configured to mate with the inferior end of the first sheath.

The sole rejection before us for review is the Examiner's rejection of claims 1-9, 12-22, 24, and 25 under 35 U.S.C. § 103(a) as obvious over McDonald[3] and Staehle[4] (Ans. 3).

DISCUSSION

The Examiner cites McDonald as describing a device for delivering multiple self-expanding stents, having all of the features of claim 1, except for the claimed loading capsule (*id.*). To meet that deficiency, the Examiner cites Staehle as disclosing a loading capsule "for releasably retaining a compressed stent" (*id.*).

Based on the references' teachings, the Examiner concludes that an ordinary artisan would have considered it obvious to combine Staehle's

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[2] Appeal Brief filed September 10, 2008.
[3] U.S. Patent No. 6,090,136 (filed June 25, 1997).
[4] U.S. Patent No. 6,132,458 (filed May 15, 1998).

teaching of a loading capsule "to a device for delivering multiple self-expandable vascular stents as per McDonald et al., the motivation to combine being the stent within the capsule of Staehle et al. 'would not be subjected to compression set due to compression for prolonged period of time'" (*id.* (citing Staehle, col. 1, lines 10-15)).

Appellants contend that the Examiner failed to make a prima facie case of obviousness because the "suggested combination is simply an impermissible hindsight reconstruction based on the teaching in the applicants' disclosure" (App. Br. 9). In particular, Appellants urge, neither reference suggests that the funnel in Staehle's device that reduces the stent's profile for advancement in the deployment tool "would even be workable with the rolled stent 13 disclosed in McDonald et al. In fact, one can imagine the rolled stent 13 of McDonald et al. becoming stuck within the funnel 19 structure of the Staehle et al. device 10 if an attempt was made to advance it therethrough" (*id.*).

The Examiner responds that "there is a reasonable expectation of success that the structure of McDonald et al. will not become stuck in the funnel structure of the Staehle et al. device" (Ans. 4). Moreover, the Examiner argues, "arguments of counsel cannot take the place of evidence in the record. Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include inoperability of the prior art" (*id.* (citing MPEP § 716.01(c)(II))).

Appellants reply by pointing out that McDonald's stent is essentially a sheet that is rolled around a mandril before deployment, and that when the rolled stent is inserted into the catheter for deployment, the outward expansion of the sheet presses the stent against the interior walls of the

catheter (Reply Br. 3). Thus, Appellants argue, placing McDonald's stent "in the receiving opening 17 in the device 10 of Staehle et al. would cause the stent 13 to unroll. There is no basis for one to believe the funnel 19 of the device 10 will cause the unrolled stent 13 to reroll" (*id.*).

We find that Appellants have the better argument.

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

As the Supreme Court pointed out in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), when determining whether the prior art gives a reason for practicing the claimed subject matter, the analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418; *see also id.* at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

In the instant case, as Appellants point out, McDonald teaches that its stent is essentially a wound or rolled perforated sheet that, when deployed,

expands radially outwardly to exert sufficient force on the interior walls of the patient's blood vessel to fix the stent in place (*see* McDonald, col. 7, l. 66, through col. 8, l. 1("The sheet 11 possesses an inherent resilience and spring force that seeks to unwind the wound layers and expand the stent lumen . . . ."); *see also, id.* at col. 7, ll. 42-44 ("The released tubular body 13 self expands in diameter to its expanded roll state constrained in size by the diameter of the body lumen at the site.")).

To pre-compress McDonald's stent before deployment, it must be rolled around a mandril (*see id.* at col. 7, ll. 23-26 ("In accordance with a method of installation using the depicted placement system 100, the perforated sheet 11 is rolled up into a tubular stent 13 such as by rolling the sheet 11 around a mandril (not illustrated)."); *see also, id.* at col. 13, ll. 39-46 (stent can be made of rolled metal heated to high temperature)).

Staehle discloses a device that stores stents in a decompressed configuration, and then re-compresses them for deployment by forcing the stents through a funnel-shaped passage mated to a deployment catheter (*see* Staehle, abstract ("funnel . . . is shaped for collapsing the self expanding stent before loading the stent into the space of the outer tube"); *see also, id.* at Figure 1).

Thus, while an ordinary artisan may have considered Staehle's device suitable for deploying certain types of collapsible stents, given that compression of McDonald's stent requires it to be rolled about a mandril, we are not persuaded that an ordinary artisan would have considered it desirable, or even suitable, to attempt to deploy McDonald's rolled stent using Staehle's device, which requires the decompressed stent to be re-compressed by being forced through a funnel. Accordingly, given the

relevant teachings in the references, we agree with Appellants that a preponderance of the evidence does not support the Examiner's prima facie case.

We therefore reverse the Examiner's obviousness rejection of claims 1-9, 12-22, 24, and 25 over McDonald and Staehle.

REVERSED

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1221 NICOLLET AVENUE
SUITE 500
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